

1 RECORD OF ORAL HEARING
2
3 UNITED STATES PATENT AND TRADEMARK OFFICE
4

5
6 BEFORE THE BOARD OF PATENT APPEALS
7 AND INTERFERENCES
8

9
10 Ex parte KENNETH F. BUECHLER,
11 JOSEPH M. ANDERBERG, and
12 PAUL H. McPHERSON
13

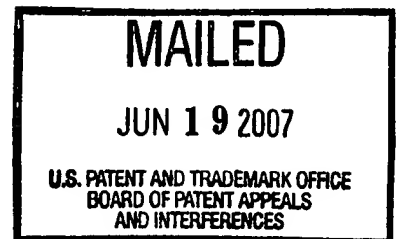
14
15 Appeal 2007-1034
16 Application 09/712,615
17 Technology Center 1600
18

19
20 Oral Hearing Held: May 17, 2007
21
22

23
24 Before TONI R. SCHEINER, DONALD E. ADAMS, and
25 RICHARD M. LEOVITZ, Administrative Patent Judges
26

27
28 ON BEHALF OF THE APPELLANTS:

29 MICHAEL A. WHITTAKER, ESQUIRE
30 Biosite
31 9975 Summers Ridge Road
32 San Diego, California 92121
33 (858) 455-4808



1 The above-entitled matter came on for hearing on Thursday, May 17,
2 2007, commencing at 10:07 a.m., at the U.S. Patent and Trademark Office,
3 600 Dulany Street, Alexandria, Virginia, before Lanieda D. Briggs, CSR No.
4 10571, Notary Public.

5 THE CLERK: Calendar number 34, Mr. Whittaker.

6 JUDGE SCHEINER: Good morning.

7 MR. WHITTAKER: Good morning.

8 JUDGE SCHEINER: Sorry our first one ran so long.

9 MR. WHITTAKER: I'm not sure if this one will take you quite
10 as long.

11 My name is Mike Whittaker. I'm the vice president of
12 intellectual property at Biosite. They are the assignees of today's
13 application.

14 The technology that we're discussing are assay devices for
15 analytes, and I'm a pretty concrete person so I find it always helps to think
16 about examples.

17 An example of this type of device or the over-the-counter
18 pregnancy tests that people encounter, and they are devices where the
19 sample is applied to a first application and it traverses through some sort of
20 device member, and the over-the-counter device is often some sort of
21 absorbant material. It could be a capillary tube or anything to a detention
22 zone that's downstream.

23 The inventors in this case asked, if, in that sort of device, you
24 get a negative result, is it a negative result because the analyte wasn't
25 present, or is it a negative result because something happened that

1 interrupted the assay procedure and it didn't take; the assay did not take
2 place?

3 And the solution that they arrived at for that problem was to
4 also incorporate into the device a discrete zone called, in the claims, a timing
5 zone.

6 And the timing zone is -- will -- the device is constructed so
7 that there is an optical component that interrogates the timing zone looking
8 for a signal and calculates from that signal whether or not the assay has
9 actually taken place or whether it is ongoing.

10 So to focus on the claims, the claims refer to an apparatus for
11 measuring the progress and time and completion of an assay comprising the
12 assay device. The assay device has a reaction chamber with an optically
13 detectable label and a diagnostic lane, and in the lane there is an assay zone
14 that is configured to bind the analyte, and a distinct timing zone.

15 The diagnostic lane is in fluid communication with the reaction
16 chamber such that when the fluid is added to the reaction chamber, it
17 traverses down and contacts the diagnostic lane and the timing zone.

18 There is an optical component in this apparatus that's
19 configured to detect an optical signal at that timing zone and generate an
20 electronic signal in response to that optical signal.

21 And then there is a signal processor that's configured to receive
22 that electronic signal and calculate a result whether or not the assay has
23 completed, and it calculates that based on one or more specifically
24 enumerated parameters, the rate of change in the amount of the signal of the
25 timing zone, or the amount of the electronic signal coming from the timing
26 zone.

1 And it doesn't seem to be disputed by the examiner that what I
2 just described is not in the cited art. Instead, the examiner contends that
3 various portions of what -- of the claim that I've just read are not actually
4 limitations. So -- and this case then turns on whether or not these are
5 actually limitations of the claim, I think.

6 So, for example, in the examiner's answer to our appeal brief,
7 the examiner refers to the configured to detect language, to an optical
8 component configured to detect an optical signal.

9 JUDGE ADAMS: That is at page?

10 MR. WHITTAKER: That is at page 13 of the examiner's
11 answer where the examiner says, "With respect to the language configured
12 to detect, this represents structural elements that must be considered."

13 JUDGE SCHEINER: Let me back up for a second. So the
14 examiner is saying that timing zones present in the -- is it Buechler?

15 MR. WHITTAKER: The examiner is saying that all that the
16 claim requires are two zones that are in fluid communication, period. That's
17 on page 12 of the examiner's answer.

18 JUDGE SCHEINER: This is actually in response to your
19 argument?

20 MR. WHITTAKER: This is in response to our arguments, yes.
21 | So the -- where we say that the time gate in the Buechler, cited Buechler
22 reference, doesn't, there is no measurement taken at that zone.

23 But the time gate at the Buechler reference is a location which
24 holds the fluid flow through a device for some period of time, but there is
25 nothing measured there, nothing in the Buechler reference tells you to
26 measure anything there.

1 JUDGE SCHEINER: But the examiner's position, as I
2 understand it, is that that time gate is in fluid communication with the
3 reaction chamber?

4 MR. WHITTAKER: Yes, and that's all that the claim requires.

5 JUDGE SCHEINER: Okay.

6 MR. WHITTAKER: The examiner says that on page 12, that's
7 all the claim requires. Merely, there are two zones and they are in fluid
8 communication with one another and that the configured-to-detect language
9 is not structural. The structural elements have not been included in the
10 claims. That's on page 13.

11 JUDGE LEBOVITZ: I'm sorry. This is element B we're
12 talking about?

13 MR. WHITTAKER: This is element B, yes.

14 JUDGE LEBOVITZ: So the examiner is saying that it doesn't
15 have an optical component?

16 MR. WHITTAKER: But that's not a limitation. Any optical
17 component no matter what it is doing in an apparatus meets that limitation.

18 JUDGE LEBOVITZ: What is the optical component in your
19 device or what kinds of things could it be?

20 MR. WHITTAKER: It's going to -- as it says, it's an optical
21 component configured to detect an optical signal from the label in the timing
22 zone, so if the label is, for example, a luminescent label, it could simply be
23 some sort of photon detector.

24 If it were a fluorescent label, it would also include some sort of
25 excitation source, and because it's configured to detect at the timing zone,

1 presumably it has to be positioned relative to the device so that it can
2 interrogate that timing zone.

3 JUDGE SCHEINER: So would it be your position that to the
4 extent that Buechler has an optical component, it's not in the correct
5 relationship to the timing . . . ?

6 MR. WHITTAKER: It's not configured to detect any -- if what
7 you are talking about is the time gate, there is nothing in Buechler that
8 instructs you to collect any data from that location.

9 JUDGE ADAMS: And that's relevant because of part C of this
10 claim where you then take that information you gathered at this gate, process
11 it to determine whether the reaction is complete or not before you let that,
12 whatever it is, bleed through to the next.

13 MR. WHITTAKER: It's not a question of allowing it to move
14 through.

15 The simplest way to understand this is as that label is being
16 mobilized down the lane, if you look at the examples what the inventors
17 have done is interrogate this timing zone, and as the label moves down the
18 unbound label, you'll begin to see an increase in signal at this timing zone,
19 and as the label washes through, that signal will fall off.

20 JUDGE ADAMS: Isn't that like chromatography?

21 MR. WHITTAKER: It is a chromatography. You are looking
22 at a front through a device, yes. You are looking at the mobilization of that
23 label through the device.

24 JUDGE ADAMS: So you have the chromatography column
25 hooked up to your optical reader, connected to a plotting chart, and you are
26 watching your --

1 MR. WHITTAKER: You are watching the label fall through.

2 JUDGE ADAMS: The label falls through. As the label passes
3 through the chromatography column, it measures the progress based on the
4 peaks on your chart.

5 MR. WHITTAKER: That is one way you can -- one analogous
6 system. Although in this case you are then using that information to decide
7 whether or not an assay has taken place at a different zone in the device.

8 JUDGE ADAMS: That's where? Part C?

9 MR. WHITTAKER: That's part C.

10 JUDGE LEOVITZ: Where is the -- is there any optical
11 component of the Buechler device?

12 MR. WHITTAKER: The Buechler device describes an assay
13 device that is designed to allow controlled fluid movement without any
14 external application of force. It's a load-and-forget-type device. And it's just
15 -- it's talking about just an assay device.

16 The time gate in that device is intended to -- it's placed between
17 the reaction chamber that's described in our case and the diagnostic zone,
18 and what it's doing is holding the fluid at that point so that in the reaction
19 chamber, there is enough time for the label that's there to be redissolved and
20 react with whatever is going on in that reaction chamber.

21 They describe it as being -- it's a hydrophobic zone that slowly
22 becomes hydrophilic from binding materials in the fluid, so that once it
23 becomes sufficiently hydrophilic, then flow continues through the device.
24 It's not intended to measure any reaction -- that a reaction has taken place. It
25 is merely to hold fluid flow for a specified period of time.

1 JUDGE SCHEINER: Let's focus on that word, "intended." But
2 for the -- does Buechler have any optical component at all?

3 MR. WHITTAKER: Not in his reference. He's added a
4 secondary reference that has an optical component.

5 JUDGE SCHEINER: So if we just look at claim 27, clause A2,
6 where we talked about the timing zone -- or a timing zone or --

7 MR. WHITTAKER: If you just look at part A --

8 JUDGE SCHEINER: And it's in fluid communication with the
9 reaction chamber, so we've got an assay zone and a timing zone separate
10 from each other within this diagnostic lane. But there is nothing in here in
11 this clause, per se, that says that the timing zone cannot come before the
12 assay zone.

13 MR. WHITTAKER: No, certainly not. And, in fact, the timing
14 zone in part A, I mean, you could have just as easily have called these zone
15 1 and zone 2. It's just a label at that point.

16 JUDGE SCHEINER: I understand. In your example the timing
17 zone is distal.

18 MR. WHITTAKER: In the example it's downstream, yeah.

19 JUDGE SCHEINER: But the claim doesn't require that.

20 MR. WHITTAKER: The claim doesn't require that.

21 JUDGE SCHEINER: So to the extent the examiner is saying
22 you have a zone separate from the assay zone in fluid communication with
23 the reaction chamber --

24 MR. WHITTAKER: It has two zones and they are separate.

25 JUDGE SCHEINER: So the examiner is on pretty solid ground
26 there, but your position is that -- or you can tell me if this is your position.

1 Buechler doesn't have an optical component. There is no reason to add an
2 optical component to Buechler in any kind of configuration.

3 MR. WHITTAKER: I'm not sure I'd say that.

4 JUDGE SCHEINER: Okay.

5 MR. WHITTAKER: To that extent. There is certainly a reason
6 to put an optical component in Buechler to read the result of the assay.
7 There is nothing in Buechler or any of the other cited references that
8 discusses that the problem that is being solved here is even a problem.

9 JUDGE SCHEINER: Right.

10 MR. WHITTAKER: Or how it might be solved.

11 JUDGE SCHEINER: I'm trying to understand how we get
12 around the intended use. When you read the specification, the timing zone is
13 there to register an IAC, an independent assay control. That's not in the
14 claim.

15 MR. WHITTAKER: I think I understand. I think I understand
16 where you are going. And I think we understood when we wrote the claim
17 that if you just -- if all you recited was that there was a timing zone and an
18 assay zone, it would depend on what the definition of timing zone was. And
19 so we tried to define in the claim the other elements that interact with the
20 timing zone.

21 So you have the optical component configured in a specific
22 fashion and you have a processor configured in a specific fashion. And that
23 configured-to language, as I understand it, is fairly common language in this
24 type of claim for describing the interaction between elements of a device.

1 And what the examiner I believe is saying, is that that is not
2 structural language. That is merely intended use language and I can ignore
3 it. If the examiner is correct, I think, the claim is probably not allowable.

4 JUDGE LEBOVITZ: Can I ask a question about C, because
5 that's what I was getting at. I mean, if you have got -- again, you have two
6 chambers and you put an optical device anywhere, okay, it looks like you
7 have almost everything except C.

8 But C says, "The signal processor configured to receive said
9 signal and determine progress at time of the completion in said assay," so --
10 "of a rate of change of the amount." So I'm wondering, could one processor,
11 could one optical component do that?

12 What you have, if you have chromatography -- let's say you
13 have a chromatography hooked up somewhere. You are measuring, you
14 know, the passage of components through the chromatography matrix if
15 that's sort of your separation step?

16 MR. WHITTAKER: Sure.

17 JUDGE LEBOVITZ: I don't understand the rate of change of
18 the amount of the signal. I mean, I know what those words mean, but to me
19 that implies that you are taking multiple measurements.

20 MR. WHITTAKER: You are in time. That's exactly right.

21 JUDGE LEBOVITZ: So how is a signal processor configured
22 to receive multiple measurements if it was on all of the time and collecting
23 data all of the time?

24 MR. WHITTAKER: You simply interrogate the spot
25 repeatedly.

1 JUDGE LEBOVITZ: But if you had a signal processor there,
2 let's say, the photon detector.

3 MR. WHITTAKER: The photon detector is the optical
4 component.

5 JUDGE LEBOVITZ: The photon detector is the optical
6 component. I don't know what it was being combined with, and the photon
7 detector, well, of course, you could turn it on and start collecting data that
8 would be configured to, you know, to detect, you know, the progressing time
9 of completion because the reaction is going through -- is passing across the
10 photon detector since it's flowing.

11 MR. WHITTAKER: Yeah, so I'm not sure I understand the
12 question.

13 JUDGE LEBOVITZ: So if the examiner's rejection is you just
14 put an optical component onto it, and if the optical component has the
15 feature of being able to be on all of the time, then it would meet limitation C,
16 because if it's on all of the time, then it can detect progress of the reaction.

17 MR. WHITTAKER: Where is the calculation? Where is the
18 component that's doing the calculation of whether or not that reaction is
19 under completion or not? And remember the optical component can't be
20 anywhere in the device. It has to be able to interrogate this distinct timing
21 zone spot. If it's pointed at the analyte detection location, it's not pointed at -

22 -

23 JUDGE LEBOVITZ: But, I mean, still -- but it doesn't require
24 it to be at any point, so even if it's the analyte detection, if you are having a
25 flowing reaction --

1 MR. WHITTAKER: No, it does, it requires that it be a separate
2 location. Part B -- or part A requires that it be a separate location on the
3 diagnostic.

4 JUDGE LEBOVITZ: Separate from the assay zone?

5 MR. WHITTAKER: Yes.

6 JUDGE LEBOVITZ: So it cannot be in the assay zone?

7 MR. WHITTAKER: Right.

8 JUDGE LEBOVITZ: So that's important then.

9 JUDGE ADAMS: To build on the first part of your question,
10 as I'm understanding this, going back to the chromatography example, you
11 walk in, you turn on the chromatography column in which your sample
12 passes through.

13 If that passes through an optical which puts a plot out on a
14 printer, you watch that plot, and until your sample falls, you know, comes
15 off, and you turn off the machine. Is that turning off is your part C, where
16 it's actually part of this device; is that right?

17 MR. WHITTAKER: Although in the chromatography example
18 there is not an assay that's been run.

19 JUDGE ADAMS: I understand. I'm parsing out trying to
20 define C here.

21 MR. WHITTAKER: Yes, they are individual steps in -- or
22 individual components of the device.

23 JUDGE LEBOVITZ: It doesn't say configured to receive, to
24 me, is sort of a mechanical localization.

25 MR. WHITTAKER: It's intended to be.

1 JUDGE LEOVITZ: Right, but it doesn't say a signal
2 processor, you know, having the means to calculate getting into the
3 computer means. In other words, there is some software loaded on it that's
4 able to do that calculation.

5 MR. WHITTAKER: I think it does, in that it says, "A signal
6 processor configured to receive and to determine." You don't stop reading.
7 "It's configured to receive the electronic statement. It's configured to
8 determine the process and timing completion."

9 JUDGE LEOVITZ: Does specification support that
10 "configured to receive and determine" means the hardware location and the
11 software loaded on it?

12 MR. WHITTAKER: I would have to look back.

13 JUDGE LEOVITZ: But that's your position?

14 MR. WHITTAKER: It certainly is. I know that, at page 14
15 where we are discussing in the specification now around line 16, it's
16 certainly discussing an assay device, an optical component and the signal
17 processor.

18 And the signal processor can determine the progress in
19 completion of time of the assay from the rate of change of the amount of
20 signal or the absolute amount or both. That sort of language I do believe the
21 spec would support that. And I don't think it's the examiner's position that
22 the specification doesn't support that.

23 The examiner's position is that the language in part C about
24 what the signal processor is doing is merely intended use language and I can
25 ignore it.

1 JUDGE ADAMS: I have a question about that. You have laid
2 out, I think, the issue here where the examiner's position is this language of
3 "configured to receive and determine" is just intended use.

4 MR. WHITTAKER: Yes.

5 JUDGE ADAMS: Your position is no, it's not intended use.
6 That's a critical embodiment of my claim.

7 MR. WHITTAKER: Yes, structural limitation of the claim.

8 JUDGE ADAMS: You come to us and say, who has the better
9 argument? Right? What is the evidence or precedent that you are relying
10 upon to support your position?

11 MR. WHITTAKER: The two cases that -- honestly, I have not
12 found anything that's binding on this board. There are numerous cases and
13 I've cited a couple of them in the brief where -- that are not citable as
14 precedent but are cited as persuasive authority. This is standard language
15 that people use in this sort of claim to describe the relationship of
16 components in a device.

17 Honestly, I'm not sure what sort of language other than this sort
18 of language could better describe the configuration within a device like this
19 given that we have to deal with English, and I'm not sure how else you
20 would describe it, honestly.

21 JUDGE SCHEINER: I just wanted to point out I was looking
22 through the rejection again and Buechler does have an optical system
23 according to the examiner at column 20, lines 22 to 31. Buechler has, let's
24 see, a Minolta Chromometer.

25 JUDGE LEOVITZ: Column 20?

1 JUDGE SCHEINER: Column 20, starting at line 22, to read
2 the color as it appears in the assay zone or something equivalent to.

3 MR. WHITTAKER: I see that, yes. I see that.

4 JUDGE LEOVITZ: But in your claim, the optical component
5 is separate -- is that the word for it -- separate from the assay zone?

6 MR. WHITTAKER: No, the timing zone is separate from the
7 assay zone.

8 JUDGE LEOVITZ: Yeah, and the timing zone is --

9 MR. WHITTAKER: So the cite that the optical component is
10 interrogating is in a different location.

11 JUDGE SCHEINER: So this would, in your opinion, require a
12 specific physical relationship between the timing zone and the optical
13 component that Buechler doesn't have?

14 MR. WHITTAKER: Yes.

15 JUDGE LEOVITZ: So the optical component is detecting
16 label in the timing zone?

17 MR. WHITTAKER: Yes.

18 JUDGE LEOVITZ: As stated in B?

19 MR. WHITTAKER: Yes.

20 JUDGE LEOVITZ: And in Buechler it is in the assay zone?

21 MR. WHITTAKER: Yes, and as I say, I think this turns on
22 whether or not those are actually limitations in the claim or whether they are
23 -- whether they are just intended use language.

24 JUDGE ADAMS: So the issue is pretty narrow. If we find
25 these are intended use limitations, you agree that the claim --

1 MR. WHITTAKER: If they are intended-use limitations, all
2 the claim requires is two spots and an optical detector and a processor.

3 JUDGE ADAMS: And the reference meets those.

4 MR. WHITTAKER: And lots of things have those elements.

5 JUDGE ADAMS: Okay.

6 JUDGE SCHEINER: There were a couple of 112 rejections. I
7 don't know if you want to spend any time on those. What about the
8 definiteness rejection?

9 MR. WHITTAKER: The definiteness rejection, I think all of
10 these are really based on the same, what I believe is a misconception of how
11 you analyze this sort of claim by the examiner.

12 The examiner -- I mean, I'm a little confused. When the
13 examiner says the term "timing zone" is a relative term, for the life of me, I
14 can't figure out what it's relative to. But --

15 JUDGE SCHEINER: I think that's probably covered pretty
16 well in your brief, those two.

17 MR. WHITTAKER: I think so.

18 And the written description rejection, again, the entirety of the
19 specification is discussing control zones that are separate from the assay
20 zones.

21 So to focus on one portion of the specification and say that the
22 disclosure does not support -- the examiner's rejection is that the
23 specification does not support a timing zone that is separate from the assay
24 zone, and, I mean, plainly the example has a timing zone that is separate
25 from the assay.

1 JUDGE SCHEINER: That would be example 15?

2 MR. WHITTAKER: That would be example -- yes, that would
3 be example 15. There is also language on page 40 where it begins
4 discussing the timing zone control.

5 Actually, on page 41 it says, "A preferred location of timing
6 zone is downstream," but really, all it requires is that it be in a discrete zone.
7 And a discrete zone is defined as being -- a discrete zone is just a zone that is
8 -- there is actually pretty good language for this.

9 JUDGE SCHEINER: I think you pointed to everything in your
10 brief.

11 MR. WHITTAKER: I think so. I really think --

12 JUDGE SCHEINER: And I think that we would need to decide
13 that issue.

14 MR. WHITTAKER: I think the important thing is just whether
15 or not the examiner has properly analyzed the claims.

16 JUDGE ADAMS: Thank you.

17 JUDGE SCHEINER: Do you have anything further?

18 JUDGE LEOVITZ: No.

19 JUDGE SCHEINER: Thanks for coming in.

20 MR. WHITTAKER: Thank you.

21 (Whereupon, the proceedings at 10:34 a.m. were concluded.)